

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING  
PHARMACY, INC. PRODUCTS  
LIABILITY LITIGATION

MDL No. 13-2419  
Dkt. No 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO:

## All Cases Against the Saint Thomas Entities

**MEMORANDUM OF LAW OF DEFENDANTS SAINT THOMAS HEALTH, SAINT THOMAS  
NETWORK, AND ST. THOMAS HOSPITAL IN SUPPORT OF MOTION TO DISSOLVE PROTECTIVE  
ORDERS AND LIFT STAYS BARRING CERTAIN DEPOSITIONS**

Pursuant to the Court’s Scheduling Orders and various rulings staying discovery, and in response to the Court’s order of April 26, 2016 setting the first bellwether trial for August 22, 2016,<sup>1</sup> the Saint Thomas Entities<sup>2</sup> file this motion to dissolve the protective orders and lift the stays in place to allow the depositions of: (1) NECC Insiders<sup>3</sup>; (2) Joseph Connolly and John Notarianni (“Government Witnesses”); and (3) the U.S. Food and Drug Administration (“FDA”) (all three collectively “the Stayed Deponents”).

The Saint Thomas Entities are mindful of the fact that the Court has already ruled on numerous motions to stay, and to compel or quash depositions and other discovery. However, implicit in the prior rulings was the assumption that the criminal trial would occur *before* the

<sup>1</sup> Docket #2828.

<sup>2</sup> Saint Thomas West Hospital, formerly known as St. Thomas Hospital (“Hospital”), Saint Thomas Network (“Network”), and Saint Thomas Health (“Health”) (collectively, the “Saint Thomas Entities”).

<sup>3</sup> The “NECC Insiders” are entities and individuals affiliated with NECC, including Barry and Lisa Cadden; Doug, Carla, and Greg Conigliaro; Glenn Chin; Alaunus Pharmaceutical, LLC; Ameridose, LLC; GDC Properties Management, Inc.; Medical Sales Management, Inc.; and Medical Sales Management, SW, Inc.

bellwether trials in this MDL. *See, e.g.*, Docket #2123 at 21 (“The Court realizes that precluding the FDA’s deposition until resolution of the criminal case might mean that the Tennessee Clinic Defendants will be unable to take the deposition of the FDA *prior to the conclusion of common fact discovery in these cases.*” (emphasis added)); Docket #2556 (“The depositions of Joseph Connolly and John Notarianni are *stayed until the conclusion of the first criminal trial* at which they testify or further order of the Court.” (emphasis added)). That assumption is no longer true. And the Court’s prior orders contemplated that changed circumstances might necessitate revisiting whether and when depositions of NECC-related individuals and entities, and of the FDA, should occur. *See* Docket #2123 at 15 (“The Court is persuaded that the depositions of the Insider Defendants who are defendants in the criminal case should not go forward *at this time.*” (emphasis added)).

This motion is necessitated by the untenable position the Saint Thomas Entities are in, due to the confluence of key witnesses still needing to be deposed, the FDA and the U.S. Attorney’s opposition to key civil discovery prior to the criminal trial, and the continuance of the criminal trial from April to September 8, 2016—all with the first bellwether trial now scheduled for August 22. As a result, the Saint Thomas Entities face a substantial prejudice that should not occur under the modern rules of civil procedure, the Due Process clause, or fundamental fairness. They should not be forced to trial before the criminal case while at the same time being denied highly relevant, admissible, readily obtainable evidence on the basis that the criminal case has yet to occur.

Specifically, the Saint Thomas Entities—whose liability in this litigation is predicated entirely on STOPNC’s actions in administering the contaminated steroids from NECC<sup>4</sup>—have three primary lines of defense<sup>5</sup> in this MDL:

- 1) STOPNC did not commit medical negligence by purchasing medication from NECC;
- 2) those who caused or contributed to the contamination are solely responsible for Plaintiffs’ injuries;<sup>6</sup> and
- 3) STOPNC was not the actual or apparent agent of any of the Saint Thomas Entities nor did the Saint Thomas Entities owe any duties to patients receiving medical care at STOPNC.

The Saint Thomas Entities’ ability to obtain discovery relevant to the first two defenses has been blocked by the various protective orders and stays of discovery that the government, the criminal defendants, and non-parties have obtained. Now that it is clear that these depositions cannot occur after the criminal trial (because the civil trials will begin first), the Saint Thomas Entities ask the Court to permit the depositions to proceed with safeguards in place that should ameliorate the concerns of the various persons who have sought to stay discovery.

Alternatively, the Saint Thomas Entities request that the Court stay the bellwether trials until after a verdict or plea agreement is reached in *U.S. v. Cadden*, and incorporate by reference their prior motion to stay and memorandum in support. *See Motion for Relief as to Proposed Bellwether Trials and Brief in Support* (“Motion to Stay”), Docket ##2785, 2786. The solution advocated by the PSC—that the Saint Thomas Entities should simply be deprived of discovering,

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<sup>4</sup> As the Court is aware, the Saint Thomas Entities did not inject any of the Tennessee patients with the NECC-compounded steroids, but have been sued based on their corporate relationship to STOPNC. If STOPNC is not liable to the Tennessee Plaintiffs, the Saint Thomas Entities cannot be liable to them.

<sup>5</sup> The term “defense” is not intended to mean affirmative defenses in this context. Instead, it means the issues that the defendants will have to develop in order to defend themselves at trial. As such, it includes both matters on which Plaintiffs bear the burden of proof, such as causation, as well as affirmative defenses.

<sup>6</sup> Defense two relates to proximate cause and comparative fault under Tennessee law.

let alone presenting, evidence crucial to their defenses—is untenable and unfairly prejudicial. In light of the substantial overlap between the criminal and civil cases, the minimal prejudice to the Tennessee Plaintiffs if the bellwether trials are stayed, and the substantial hardship Defendants would suffer if forced to proceed to trial without being able to obtain the facts they need to defend the claims made against them, as well as the other *Microfinancial* factors,<sup>7</sup> the Court should defer the civil actions until the criminal case is tried.

### ARGUMENT

#### **I. The Interests of the Government and the Criminal Defendants Can Be Protected**

The government has sought to stay the depositions of Joe Connolly and John Notarianni and to block the FDA’s deposition by protective order because it is concerned the criminal defendants will obtain evidence they are not otherwise entitled to in a criminal proceeding. Conversely, the criminal defendants, related entities (and certain third-parties), have raised blanket objections to testifying and also sought protective orders. The Court has largely granted these motions, curtailing or deferring discovery as to most of the NECC Witnesses and the FDA. Docket ##2123 at 22 (granting protective orders as to NECC Insiders and the FDA); 2354 at 1 n.1 (granting government’s request to intervene); 2403 (granting interim stay of depositions of Connolly and Notarianni); 2556 (staying deposition of Connolly and Notarianni until conclusion of criminal trial or further order of the Court).

Now that the civil trials are scheduled to commence first, however, the depositions can no longer be delayed. The depositions must either be allowed to proceed before trial, or the Court must go beyond its prior rulings and rule that the Saint Thomas Entities will be denied access to

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<sup>7</sup> *Microfinancial, Inc. v. Premier Holidays Int’l, Inc.*, 385 F.3d 72, 77-78 (1st. Cir. 2004); *see also* Docket #2786 at 3-4.

this important discovery.<sup>8</sup> Importantly, there are simple procedures that the Court can implement that results in due process for all involved. The discovery can proceed under an “Attorney’s Eyes Only” designation (for review by counsel for the remaining parties to the civil cases only) and the courtroom at trial can be sealed when this important discovery is presented to the jury. Protections like this are routine and have been previously implemented in similar circumstances by this Court. *See United States v. Parcels of Land at 78-98 Middlesex St., Lowell*, No. CIV. A. 88-2424-Z, 1989 WL 73301, at \*3 (D. Mass. June 16, 1989) (Zobel, J.) (“In view of the fact that Laliberte was the target of a tax fraud investigation and a criminal defendant in a New Hampshire state court case, I entered a protective order which prohibited the use of Laliberte’s deposition transcript, interrogatory answers and affidavit against him in those proceedings.”) *aff’d*, 903 F.2d 36 (1st Cir. 1990).

## **II. The Saint Thomas Entities Need to Depose the Stayed Deponents Prior to Trial**

The Saint Thomas Entities and the STOPNC Defendants previously explained the relevance and need for these depositions, and they incorporate the Defendants’ prior briefing on this point by reference: *Opposition to the Invoking Defendants’ Motion for Protective Orders and To Quash Deposition Notices*, Docket #1869 at 5-13, *Response to United States’ Motion for Leave to Intervene and For A Stay of Certain Depositions Pending Resolution of Related Criminal Proceedings*, Docket #2275 at 3-13; and the *Tennessee Clinic Defendants’ Response to FDA’s Motion for Protective Order*, Docket #1881 at 5-9.

A party is entitled under the Federal Rules of Civil Procedure to obtain relevant discovery proportional to the needs of the case. It is an abuse of discretion to prohibit the taking of

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<sup>8</sup> While the Saint Thomas Entities do not agree with the arguments raised by the government, the criminal defendants, and others in obtaining the various discovery stays, the proposed measures protect those concerns.

depositions, unless the party opposing the deposition meets its “heavy burden of showing ‘extraordinary circumstances’ based on ‘specific facts’ that would justify such an order.” *See Prozina Shipping Co., Ltd. v. Thirty-Four Automobiles*, 179 F.R.D. 41, 48 (D. Mass. 1998); *see also Salter v. Upjohn Co.*, 593 F.2d 649, 651 (5th Cir. 1979) (“It is very unusual for a court to prohibit the taking of a deposition altogether and absent extraordinary circumstances, such an order would likely be in error.”); *Slagowski v. Cent. Washington Asphalt*, 291 F.R.D. 563, 585 (D. Nev. 2013) (denying motion to stay depositions of asphalt company drivers in a wrongful death action even though they might be prosecuted for the fatal traffic accident that led to the civil suit, and directing that they appear and assert the Fifth Amendment privilege “question by question”).

#### **A. NECC Insiders and Government Witnesses**

Testimony from the NECC Insiders and the Government Witnesses is crucial to two of the Saint Thomas Entities’ defenses: STOPNC was not negligent, and the various NECC individuals, related entities, and settled defendants collectively are responsible for all fault in causing Plaintiffs’ injuries. *See* Docket #2275 at 7-8.

As defendants in a negligence case, Saint Thomas Entities have a right to discover and present evidence that will enable juries to properly and fairly apportion fault among the various alleged tortfeasors. *See McIntyre v. Balentine*, 833 S.W.2d 52, 58 (Tenn. 1992). Because Tennessee provides for comparative fault, the Saint Thomas Entities are entitled to show the jury at trial how the individuals and entities related to the NECC operation are responsible for Plaintiffs’ injuries. *See Banks v. Elks Club Pride of Tenn.*, 1102, 301 S.W.3d 214, 223 (Tenn. 2010); *Owens v. Truckstops of Am.*, 915 S.W.2d 420, 430 (Tenn. 1996). The juries will therefore be asked to consider the fault of several others in causing each Plaintiff’s injuries:

- NECC failed to properly compound the MPA to eliminate the fungal contamination by, among other things, failing to autoclave the MPA according to the standards of United States Pharmacopeia (“USP”) 797 and NECC’s own written procedures, failing to terminally sterilize the MPA, and failing to conduct final product testing as also required by USP 797, which would have identified the contamination before it reached any patient.
- The fungus that contaminated the MPA entered the cleanroom from gaps in the ceiling grid that were misaligned by Liberty Industries at the time the cleanroom at issue was installed in 2006.
- ARL BioPharma, Inc. failed to perform USP 71 testing on each of the three lots of contaminated MPA.
- UniFirst Corporation, the company with sole responsibility for cleaning the walls and ceilings of the cleanroom where the MPA was compounded, failed to devote the time needed to properly clean, and failed to use proper cleaners or technique.

These are not defenses based on pieces of paper. The evidence can and needs to be elicited through the testimony of witnesses. The value of eyewitness testimony cannot be underestimated, such as that from Joe Connolly, who can explain how NECC was actually compounding medications compared to what they were telling their customers they were doing. Or the testimony of John Notarianni, the NECC salesman for STOPNC, who will explain the sales process that was used to provide comfort and assurance to customers that NECC only made and sold the highest quality medications available. This proof is not available from other sources. The story of how NECC and its marketing wing MSM were run, including how product was actually made, is a key part of the bellwether trials, and only fact witnesses with personal knowledge can take the stand and provide that sworn testimony. In light of all of the witnesses who are pleading the Fifth, it is hard to imagine any trial going forward—at least one based on Due Process that seeks the truth—without the testimony of these two witnesses.

A separate reason why the Saint Thomas Entities have a need and right to these depositions is to refute any attempt by the PSC to prove causation. Under Tennessee law, a third

party's criminal act relieves a defendant of liability where such act is not reasonably foreseeable. *See, e.g., Alexander v. Zamperla*, No. 09-01049-COA-R3-CV, 2010 WL 3385141, at \*4 (Tenn. Ct. App. Aug. 27, 2010); Docket #2275 at 8. Proof that NECC and its employees committed unforeseeable crimes will thus constitute a superseding cause, breaking any proximate causal link between STOPNC (and, by extension, the Saint Thomas Entities) and Plaintiffs' injuries.

The need for this evidence is particularly pressing for reasons beyond the Saint Thomas Entities' control. As detailed in the Saint Thomas Entities' Motion for Relief as to Bellwether Trials, now that the PSC has secured substantial settlements from NECC and the other parties who are actually responsible for this tragedy, the PSC is now questioning whether the settled entities caused the outbreak at all. Docket #2786 at 11-14. The reason for the PSC's about-face is obvious: the PSC hopes the juries will fail to assign the requisite degree of fault where it properly lies: with NECC, Liberty, ARL, UniFirst and the regulators.

Even if any individuals invoke their Fifth Amendment privilege as to most questions, that very invocation is relevant and admissible in a civil action. *See Saint Thomas Entities' Opposition to Motions for Protective Orders*, Docket #1869 at 8-9; *S.E.C. v. Jasper*, 678 F.3d 1116, 1125-27 (9th Cir. 2012); *Hinojosa v. Butler*, 547 F.3d 285, 294-95 (5th Cir. 2008); *Curtis v. M&S Petroleum, Inc.*, 174 F.3d 661, 674-75 (5th Cir. 1999). As discussed below, allowing the questioning of such a witness before the jury is also consistent with the First Circuit's consistent refusal to permit blanket assertions of the privilege.

For any and all of these reasons, the Court should dissolve the protective order precluding depositions of the NECC Insiders, Docket #2123 at 22, and lift the stay on deposing the Government Witnesses, Docket #2556.



**B. The First Circuit Rejects Blanket Assertions of the Fifth Amendment—The Individual Deponents *Must* Appear, And Assert The Privilege Question-By-Question**

**1. First Circuit Precedent Bars Blanket Assertions of Privilege**

In the First Circuit, blanket assertions of the Fifth Amendment are improper and are barred by plain language in binding precedents. “*The privilege cannot be invoked on a blanket basis.*” *United States v. Castro*, 129 F.3d 226, 229 (1st Cir. 1997) (emphasis added) (citing *In re Grand Jury Matters*, 751 F.2d 13, 17 n.4 (1st Cir. 1984)). “It operates question by question.” *Id.* “[W]hile [a defendant] certainly had a right to refuse to answer questions on the basis of her privilege against self-incrimination, *it was improper to refuse to appear for any deposition whatsoever* on that basis, rather than refuse to answer specific questions.” *Vazquez-Rijos v. Anhang*, 654 F.3d 122, 129 (1st Cir. 2011) (emphasis added). “A district court inquires into the reasons a witness is claiming the Fifth Amendment privilege to verify that the witness is not invoking the privilege ‘on a blanket basis.’” *United States v. Ramos*, 763 F.3d 45, 55 (1st Cir. 2014) (citing *Castro*, 129 F.3d at 229).<sup>9</sup>

**2. Contrary Cases From Other Circuits Are Not Applicable Here**

As the Court previously noted, the D.C. Circuit and Ninth Circuit have recognized the possibility of a blanket assertion in “‘unusual cases.’” Docket #2123 at 13 (citing *United States v. Ortiz*, 82 F.3d 1066, 1073 (D.C. Cir. 1996); *United States v. Moore*, 682 F.2d 853, 856 (9th Cir. 1982)). However, that is not the law here. *Ramos*, 763 F.3d at 55; *Vazquez-Rijos*, 654 F.3d at 129; *Castro*, 129 F.3d at 229. Notably, there are no reported decisions by the First Circuit

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<sup>9</sup> The closest the First Circuit has come to suggesting a blanket assertion is permitted was in a criminal trial in which the defendant attempted to call government informants to testify: “Blanket claims of privilege are not favored as to mere witnesses who may have some unprivileged information to contribute.” *United States v. Santiago*, 566 F.3d 65, 70 (1st Cir. 2009). But in *Santiago*, the witnesses in fact asserted the privilege question-by-question during voir dire away from the jury. *Id.* And as the quote above demonstrates, *Santiago* emphasized how rarely it is proper for a witness (as opposed to a criminal defendant in his own trial) to assert a blanket privilege. *See id.*

citing *Ortiz*, *Moore*, or the decision on which *Ortiz* rests, *United States v. Thornton*, 733 F.2d 121 (D.C. Cir. 1984), on the question of whether a blanket assertion is proper.

Actual examples of a blanket assertions being upheld are rare—neither *Ortiz* nor *Moore* actually upheld a blanket assertion. See *Ortiz*, 82 F.3d at 1072-73 (recognizing existence of exception in the D.C. Circuit, but not applying it); *Moore*, 682 F.2d at 856-58 (holding that district court erred in allowing blanket assertion). Consistent with the holding in *Moore*, the District Court of Nevada—facing similar issues to those present here, namely some co-defendants seeking a protective order staying their deposition pending a criminal investigation—squarely held that blanket assertions were improper, and ordered that “[t]he parties may depose the individual defendants, and the defendants can assert their Fifth Amendment privilege on a ‘question by question’ basis.” *Slagowski*, 291 F.R.D. at 585.

Even if blanket assertions were allowed by First Circuit precedent, the D.C. Circuit’s opinion in *Thornton* illustrates why it should not be allowed in this case. *Thornton*, cited by *Ortiz* on this point, concerned criminal defendants attempting to call a fellow criminal defendant to testify at trial regarding the same crime. It was considered to be an “unusual case” for two reasons. First, “the defendant and the witness [invoking the privilege at trial] were arrested at the same time on similar charges, arising out of activities in which they very well might have been jointly involved.” *Thornton*, 733 F.3d at 126. Second, no effort had been made by the examining counsel to obtain a question-by-question invocation of the privilege:

Perhaps if the defense counsel had proffered a particular line of questioning, supported by reasons to believe that the witness would not invoke his [F]ifth [A]mendment privilege as to those questions, the district judge might have permitted such questioning. In this case, however, the defense counsel made no such proffer; instead, the defense counsel asked broadly, “Would you, at this point, tell His Honor what happened at that time?”

*Id.* at 126-27. As explained previously, the Saint Thomas Entities do intend to ask questions of these witnesses that would not implicate their privilege against self-incrimination, such as establishing background facts and authenticating documents.

Under comparative fault, the jury is entitled to hear all of the facts and circumstances and to assess the credibility of witnesses in deciding how to allocate fault. Even if a witness pleads the Fifth to all substantive testimony, a jury is entitled to be introduced to the witness, particularly to key witnesses like Barry Cadden. Any jury hearing an NECC bellwether case should hear Mr. Cadden explain where he grew up, where he went to school, what he did for employment before NECC, etc. Importantly, there are many players in this docket, and a jury should be able to hear Mr. Cadden explain familial relations connections, such as who is his wife (business partner and fellow pharmacist Lisa Conigliaro Cadden), who are the Conigliaros, etc. There is no substitute for seeing a person testify, hearing his or her voice, understanding his or her background, and ultimately (on a question-by-question basis), hearing him or her refuse to answer a specific question for fear of self-incrimination. *See Serafino v. Hasbro, Inc.*, 82 F.3d 515, 518 (1st Cir. 1996) (“The district court found that ‘there are no company records or other Hasbro employees whose information could effectively substitute for responses from George Serafino himself.’ We agree. Even if a paper trail might show some irregularities, it is a poor proxy for Serafino’s testimony [regarding his alleged illegal conduct].”); *Jasper*, 678 F.3d 1116 at 1125 (affirming trial judgment where “the district court allowed the SEC to introduce evidence of [defendant]’s repeated invocation of the Fifth Amendment and instructed the jury that it could, but was not required to, draw an adverse inference from the invocations”); *Rosebud Sioux Tribe v. A & P Steel, Inc.*, 733 F.2d 509, 522 (8th Cir. 1984) (concluding that the trial court erred by not allowing testimony from a witness intending to plead the Fifth **and granting a new trial**);

*Brink's Inc. v. City of New York*, 717 F.2d 700, 702-04 (2d Cir. 1983) (affirming trial ruling that a party's former employees, who were fired for stealing money from parking meters and were invoking the Fifth Amendment, could be called by the opposing party as trial witnesses, and the ex-employee's reliance on the Fifth Amendment was circumstantial evidence of their former employer's breach of contract and negligence); *see also* Docket #2275 at 2-5.

Until questions are actually put before each deponent, there is no way of knowing what questions they may in fact be willing to answer. *Cf. Brink's Inc.*, 717 F.2d at 705 (“And despite the fact that the City had good reason to believe that the witnesses would assert their privilege when called, there was always the possibility that one of the defendants, after pleading guilty or being convicted, might ‘come clean’ on the witness stand as a matter of conscience.”).

### **3. Question-by-Question Invocations Are Necessary to Establish Full and Effective Adverse Inferences and Will Not Prejudice the Criminal Trial**

There is a further reason why the NECC Insiders should be required to appear, and invoke the privilege question-by-question. In at least one instance, a court has denied a request for adverse inferences precisely because the potential witness was never forced to invoke the privilege question-by-question, holding the movant should have filed a motion to compel the potential witness's deposition. *Prime Media Group, LLC v. Acer Am. Corp.*, No. 12-CV-05020-BLF, 2015 WL 527836, at \*4 (N.D. Cal. Feb. 6, 2015).

Lastly, requiring the individual deponents to invoke the privilege question-by-question will not prejudice them in *U.S. v. Cadden*, for at least three reasons. First, under an attorney's eyes only designation, the government will not have access to these depositions. And second, the presiding judge in *Cadden* would be required to bar any attempt by the government to use the invocation of the privilege against any of the criminal defendants. *See United States v. Johnson*, 488 F.2d 1206, 1211 (1st Cir. 1973) (holding that, in a criminal case “neither side has the right to

benefit from any inferences the jury may draw simply from the witness' assertion of the privilege either alone or in conjunction with the questions that have been put to him").

Finally, these deponents no longer have any risk of individual liability to the civil Plaintiffs because of the NECC settlement. Their submission on the comparative fault question is solely for purposes of allocating the blame to any wrongdoers found by the jury according to the magnitude of their role in causing the harm and as required by Tennessee law.

Accordingly, if the civil case will be proceeding before the criminal, all individual deponents should be required to appear for deposition. They can assert the Fifth Amendment privilege question-by-question, which will in turn permit the Court to perform its role: to conduct a "particularized inquiry" based on the specific questions asked. *Vazquez-Rijos*, 654 F.3d at 129; *Castro*, 129 F.3d at 229-30. Doing so also enable the Court to determine specific, sufficient adverse inference instructions where required.

### **C. The FDA**

The FDA likewise should submit to a 30(b)(6) deposition. The FDA's testimony is highly relevant to many aspects of this case, again going to two of the Saint Thomas Entities' defenses: STOPNC was not negligent and the acts and omissions of third parties caused and contributed to Plaintiffs' injuries.

As to the first, the FDA failed to exercise adequate regulatory oversight over NECC, leaving it in business until the worst happened. Given the lack of action by the FDA, NECC was permitted to continue selling drugs across the country.

As to the second, the FDA will be able to provide vital, disinterested testimony as to the condition of NECC's premises when it conducted its inspection in 2012 and its testing and findings. As the Court is aware, members of the PSC had access to NECC's premises soon after the FDA's 2012 inspections, while the Saint Thomas Entities were not granted access to the

NECC facility until more than a year later (July 2014). The FDA's testimony about its inspection will be important evidence in showing the juries that NECC and related parties—not STOPNC—caused this tragedy. And, the Saint Thomas Entities believe that fault should be apportioned to the FDA itself.<sup>10</sup> The FDA (and Massachusetts Board of Registration in Pharmacy) failed to take appropriate action against NECC despite awareness that it was operating outside of the bounds of traditional pharmacy compounding.

The FDA's deposition is only stayed at present because the government has taken the position that deposing the FDA before the criminal trial would give the criminal defendants unfair access to evidence they are not entitled to in a criminal proceeding. By conducting the deposition under an attorney's eyes only designation, with the criminal defendants and their counsel excluded, this justification evaporates. The Court should dissolve the protective order barring the FDA's 30(b)(6) deposition prior to the criminal trial. Docket #2123 at 22.

### **III. The Criminal Case Against the NECC Insiders Should be Tried First**

Alternatively, the Court should defer the civil actions until the criminal case is tried for the reasons set forth in the Saint Thomas Entities' omnibus motion for relief as to Bellwether Trial Setting. *See* Docket ##2785, 2786 ("Omnibus Motion"), which is incorporated by reference.<sup>11</sup> The criminal trial commences September 8, 2016, and the Saint Thomas Entities are unaware of any reason for it to be further delayed. Notably, on May 3, 2016, the Court presiding

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<sup>10</sup> The jury can also apportion fault to non-parties who might otherwise be immune from suit. *See Carroll v. Whitney*, 29 S.W.3d 14, 19 (Tenn. 2000).

<sup>11</sup> The Court allowed a portion of the requested relief to the extent the Omnibus Motion sought postponement of the first trial date to afford more time for *Daubert* and dispositive motions, *see* Docket #2828, but did not expressly allow or deny the Saint Thomas Entities' requests for relief in connection with the NECC Insiders' criminal trial.

over the criminal trial entered an order denying the criminal Defendants’ motion to dismiss,<sup>12</sup> removing another possible impediment to the criminal trial going forward.

**A. The Court Has Previously and Correctly Found Substantial Overlap in These Proceedings**

The Court has already found substantial overlap between the criminal and civil cases. Docket #2123 at 15-16. In addition to the arguments raised in the Omnibus Motion on this point, Docket #2786 at 4-5, the May 3, 2016 Order entered by the Court in *U.S. v. Cadden* denying the criminal defendants’ motion to dismiss also demonstrates the substantial overlap between the civil and criminal cases. *See* Docket #573, *U.S. v. Cadden*, No. 1:14-cr-10363-RGS. In its order, the Court held that the government could not prosecute violations of USP Chapter 797 as crimes *per se*, but that, if proven, the criminal defendants’ failure to comply with the USP could be considered, with appropriate and admissible expert guidance, “*on the issues of intentional misrepresentation, causation, and recklessness* (insofar as the allegations of second degree murder are concerned).” *Id.* at 18 n.10 & 22. Issues regarding causation and the NECC Insiders’ intentional misrepresentation and recklessness are critical to the Nashville Healthcare Defendants’ defense. *See* Part II above.

**B. The Delay Would Be Brief, But Critically Important to Finding the Truth**

The PSC’s argument that it will be prejudiced merely by any delay of the bellwether trials is not sufficient to show the kind of prejudice necessary to overcome the advantages that a brief delay of the civil trials would provide—solely to ensure that they are tried after the criminal trial. *See In re Enron Corp. Sec., Derivative & Erisa Litig.*, No. H-01-3624, 2003 WL 25508889, at \*2 (S.D. Tex. 2003) (“Mere inconvenience and delay do not constitute undue burden and substantial prejudice warranting a denial of a stay of discovery.” (citations omitted)).

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<sup>12</sup> *See U.S. v. Cadden*, No. 1:14-cr-10363-RGS [Docket #573].

In this case, the PSC has not articulated any particular prejudice the Tennessee Plaintiffs will suffer by such a brief delay. There is no allegation that their chances of recovery would be decreased through depletion of the Defendants' assets, as has been made in other cases (either through costly criminal defense fees or the assessment of a significant fine and/or prison sentence upon the entry of a guilty verdict). *See, e.g., Fed. Sav. & Loan Ins. Corp. v. Molinaro*, 889 F.2d 899, 903 (9th Cir. 1989) (plaintiff would be prejudiced by delay from stay of case pending outcome of any criminal proceedings where civil defendant "continued to attempt to dispose of his assets"); *Nowaczyk v. Matingas*, 146 F.R.D. 169, 175 (N.D. Ill. 1993) (in embezzlement case, burden to civil defendants of defending civil and criminal cases simultaneously outweighed by risk to plaintiff that defendants would dissipate liquidated company's funds).

Nor is there any threat of degradation of evidence. *See, e.g., U.S. ex. rel. Gonzalez v. Fresenius Med. Care N. Am.*, 571 F. Supp. 2d 758, 763 (W.D. Tex. 2008) (finding that plaintiff could be unduly prejudiced where a stay could prevent a plaintiff "from obtaining the discovery necessary to prove her case . . . because of the infirmity of potential witnesses"). None of those factors exists here, where the Plaintiffs have already settled with the criminal defendants, and where the Bellwether Plaintiffs and the Nashville Healthcare Defendants' witnesses have all been deposed (in some instances more than once).<sup>13</sup>

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<sup>13</sup> Of course, the Tennessee Plaintiffs are not the only Plaintiffs in this MDL. Numerous Plaintiffs have filed suits against health care providers in Maryland, New Jersey, and many other states. On May 5, 2016, this Court entered a scheduling order setting the deadline to complete case-specific expert depositions in the Box Hill and Premier cases for July 17, 2017, Docket #2851, which would mean a likely trial for either of those groups of cases commencing in Fall 2017. It is curious how a brief delay in the Tennessee cases would be unduly prejudicial to the Tennessee Plaintiffs when, even with a stay to allow the conclusion of the criminal proceedings, the Tennessee Plaintiffs will proceed to trial in this MDL months before any other Plaintiffs will.



By contrast, a stay would enable the discovery of previously unavailable, but unquestionably relevant, evidence. *See, e.g., Dominguez v. Hartford Financial Servs. Group, Inc.*, 530 F. Supp. 2d 902, 907 (S.D. Tex. 2008) (staying civil action during pendency of related criminal case where moving defendant would be significantly impeded in its ability to defend against civil allegations because of other defendants' expected invocation of their Fifth Amendment privilege). And the proposed deferral would be only a few months. *See In re Enron Corp.*, 2003 WL 25508889, at \*9 (rejecting plaintiffs' claims that they would be severely prejudiced by a stay where the criminal trial was expected to occur within the year). Significantly, in this case, the criminal trial is scheduled to begin ***less than a week*** after the *Wray* trial would conclude if it concludes within two weeks, and could even overlap if it extends into three or more.<sup>14</sup>

Although the majority of published opinions in this context address stays of a civil case where either a plaintiff or a defendant is also a defendant in a criminal case arising out of the same facts, courts presented with analogous issues in cases where the parties *were not* also parties to the criminal action have granted stays where necessary to achieve justice. In *Librado v. M.S. Carriers, Inc.*, a trucking company defendant in a civil wrongful death collision case successfully moved to stay discovery in part, pending the outcome of a criminal negligence homicide case against the truck driver predicated on the same collision. No. 3:02-cv-2095D, 2002 WL 31495988, at \*3 (N.D. Tex. Nov. 5, 2002). Significantly, the truck driver was *not* a defendant in the civil action at the time the stay was granted, but was joined after. *Id.* at \*1. The driver's testimony was necessary to the trucking company's defense, but that testimony was

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<sup>14</sup> As noted in the Motion to Stay, the Saint Thomas Entities estimate that the first bellwether trial will take at least three full weeks to try, and possibly longer if only half days are utilized. *See* Docket 2786 at 17-18.

unavailable because the driver was asserting the Fifth Amendment privilege. *Id.* At the same time, the plaintiffs sought to depose the driver and propounded discovery that the trucking company contended it could not respond to. *Id.*

Although the court declined to stay the matter entirely due to the amount of remaining discovery left unaffected by the criminal proceeding, the court ordered a stay of discovery relating to the truck driver and any discovery where the trucking company would be prejudiced in its response due to the driver's unavailability:

[T]he court abates the case to the extent that plaintiffs are precluded from taking Nichols' deposition and from conducting any discovery that MSC can show, by motion, ***will or is likely to subject it to undue prejudice by reason of Nichols' unavailability as a witness to MSC or to assist it in its defense.*** Based on its consideration of the above factors, and in the interests of justice, the court grants in part MSC's motion to abate and, to the extent set forth above, abates discovery in this case until such time as a verdict of not guilty has been returned or sentencing has been completed in the criminal action against Nichols.

*Id.* Similarly, in *Akuna Matata Invest., Ltd. v. Tex. Nom L.P.*, the court granted a stay of the entire case pending the conclusion of a criminal investigation and any corresponding criminal proceedings against two employees of one of the civil defendants, and possible criminal investigations of two accountants designated by the civil defendants as expert witnesses. No. 05-CV-1053, 2008 WL 2781198, at \*2 (W.D. Tex. Apr. 14, 2008). The stay was granted after the plaintiff sought to depose the four individuals who were potentially under criminal investigation. *Id.* at \*1.

### CONCLUSION

The Saint Thomas Entities had nothing to do with purchases from NECC and did not cause or contribute to the steroid contamination at issue in this MDL proceeding. They are entitled to obtain the evidence needed to prove who did—the people working in the cleanrooms at issue and those marketing NECC product and the people whose actions were not only

negligent, but criminal. The Government has promised “*overwhelming evidence* of [Barry Cadden’s and Glenn Chin’s] extreme recklessness and wanton and willful disregard for human life that *directly caused the deaths* of the twenty-five individuals named in the Indictment.”<sup>15</sup> Before a juror is asked to assign fault to a clinic or doctor who did nothing more than purchase a medication without any knowledge of that it had been contaminated, they should be allowed to hear for themselves from the people at NECC whose actions solely caused the worst outbreak of fungal meningitis in the nation’s history. By permitting the depositions to proceed, such key evidence can be obtained once and used in every bellwether proceeding, including the one set to begin before the criminal trials commence. Alternatively, and particularly if the Court determines that it cannot grant the requested relief without the risk of interference with the criminal trial, the far better course is to stay the bellwether trials until after a verdict or plea agreement is reached in *U.S. v. Cadden*.

Therefore, the Saint Thomas Entities move the court to:

- i. Dissolve the protective order barring depositions of the NECC Insiders, Docket #2123;
- ii. Lift the stay barring deposition of the Government Witnesses, Docket #2556;
- iii. Dissolve the protective order barring the 30(b)(6) deposition of the FDA, Docket #2123; and
- iv. Order that the depositions be taken pursuant to an “attorney’s eyes only” designation and for counsel to address use of these deposition transcripts at trial at the pre-trial hearing.

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<sup>15</sup> See *Government’s Opposition to Defendants’ Motion to Dismiss Count 1 (RICO) and Count 2 (RICO Conspiracy), and to Strike Murder Racketeering Acts From Count 1*, *U.S. v. Cadden*, No. 1:14-cr-10363-RGS [Docket #456] at 15 (emphasis added).

If the Court does not permit the depositions of the NECC Insiders, Government Witnesses, and the 30(b)(6) representative of the FDA, the Saint Thomas Entities request in the alternative that the Court:

- i. Stay all proceedings after the *Daubert* deadline until ten days after a verdict or plea agreement is reached in *U.S. v. Cadden*;
- ii. Permit the Saint Thomas Entities to depose Joe Connolly, John Notarianni, the FDA, and any other NECC witness within 30 days after a verdict or plea agreement is reached in *U.S. v. Cadden*;
- iii. Allow the Saint Thomas Entities to amend their expert reports relating to causation within 30 days of completing the post-criminal trial NECC discovery; and
- iv. Grant such other and further relief to which the Saint Thomas Entities are entitled.

#### **Request for Certification**

In the event the Court does not permit the depositions at issue to be taken and likewise does not stay bellwether trials until after the criminal trial such that the discovery can then be taken, the Saint Thomas Entities request pursuant to 28 U.S.C. § 1292 that the Court certify its decision for immediate appeal.

Dated May 6, 2016

SAINT THOMAS WEST HOSPITAL,  
FORMERLY KNOWN AS ST. THOMAS  
HOSPITAL, SAINT THOMAS  
NETWORK, AND SAINT THOMAS  
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\*Appearing *Pro Hac Vice*

**CERTIFICATE OF SERVICE**

This certifies that a true and accurate copy of the foregoing was served on all parties of record by virtue of the Court's electronic filing system this 6th day of May, 2016.

/s/ Sarah P. Kelly  
SARAH P. KELLY